

EXHIBIT P

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

In re: BIOMET M2A MAGNUM)
HIP IMPLANT PRODUCTS) CAUSE NO. 3:12-md-2391
LIABILITY LITIGATION)
(MDL 2391))
)

This Document Relates to: All Cases

EXPERT REPORT OF GEORGE S. KANTOR, M.D.

I. QUALIFICATIONS

Attached as Exhibit “A” and incorporated into this Expert Report is my current *Curriculum Vitae* which reflects my education, training, awards, publications, experience, and qualifications in the area of orthopedic surgery.

I received my Bachelor of Arts Degree in 1971 from Tulane University, New Orleans, Louisiana with high honors. I received my Medical degree from Tulane University in 1977. Following a one year flexible surgical internship at Charity Hospital, Tulane University I matriculated to the University of Utah from 1978-1982 where I completed my Orthopedic residency. This was followed by an 18-month post-Doctoral fellowship at the University of Southern California in Los Angeles focusing on Adult Reconstructive/Joint Replacement surgery. I have been Board Certified by The American Board of Orthopedic Surgery since 1986 with ABOS recertification in 1998 and 2009. My recertification status runs through 2020. All certifications were passed during the first sitting.

My professional honors include, but are not limited to, Bachelor of Arts with high honors 1971, Tulane University; “Golden Scalpel” award for outstanding surgical intern, Charity Hospital/Tulane University from 1977 -1978; Chief resident University of Utah from 1981-1982; and Albert E. Klinkicht award from American Academy of Orthopedic Surgery/American Orthopedic Foot Society in 1981.

Additionally, I've held the following appointments and/or positions in during my career: Johnson and Johnson Orthopedics, Inc., Clinical Consultant and Surgical Instructor from 1990-1997; DePuy Orthopaedics, Inc., Clinical Consultant and Surgical Instructor from 1997-2009; D. Network, Medical Director/Consultant, Physical Therapy/Occupational Therapy and Rehabilitation from 1997- 2005; The Gardens Court, Medical Director of Rehabilitation from 2001- 2005; Chatsworth at PGA National, Medical Director of Rehabilitation from 2001-2011; The Waterford, Medical Director of Rehabilitation from 2011-2012; Chairman Dept. of Orthopaedics, Palm Beach Gardens Medical Center from 1998-1999 and 2002-2004; Chairman Dept. of Orthopaedics, St. Mary's Medical Center from 2008-2015; Vice Chief of Staff, Palm Beach Gardens Medical Center from 2000-2002; Vice Chief of Surgery, Palm Beach Gardens Medical Center from 2000-2002; Palm Beach Gardens Medical Center, Medical Council from 2000-2002; Spokesperson, Tenet Southeast Regional Total Joint Program from 1996-2012; Presidential Advisory Council Tulane University from 2008- present; and Governing Board of Directors Tulane University Medical School from 2011-present.

Following my fellowship training, I have been in private practice for the past 3 decades at the same office and locale specializing exclusively in joint replacement of the hip, knee and shoulder. Once in practice I took part in visiting surgeon visits

to the United Kingdom. Since the inception of my private practice in Florida, I have performed approximately 12,000 total Joint procedures, 5,000 of these procedures involved total hip arthroplasty. Approximately 25-30% of my practice has involved complex revision procedures.

II. ASSIGNMENT

I am being designated as an expert in the fields of medicine and orthopaedic surgery. I will also provide fact and/or opinion testimony regarding the concept, development, design and performance of the metal-on-metal bearing surfaces, including those manufactured by Biomet Orthopedics, Inc., et al. (Biomet). I will also give general opinions regarding damages and/or injuries that may occur due to of metal on metal bearing surface failures. I reserve the right to supplement this report when further data, documents, records or information becomes available, in order to update, revise or correct this report if necessary. I may use visual aids or demonstrative exhibits that illustrate or explain my opinions.

III. MATERIALS REVIEWED

A list of the materials, including scientific and medical publications, facts or data, and internal Biomet and third party documents, that I reviewed in preparing this report is attached as Exhibit "B."

IV. OPINIONS

A. Knowledge of the History of Metal on Metal total hip replacements

Knowledge and insight I gained during my training and early experience led me to the professional opinion, developed long ago through my professional training, education, and experience, that the risk of employing metal-on-metal (MoM) bearings for either primary or revision hip arthroplasty far outweighed any supposed benefit. I continue to hold that opinion today.

Dr. Phillip W. Wiles, a British surgeon, performed one of the first MoM bearing surface total hip arthroplasty (THA) in 1938. In the years that followed, additional MoM bearing systems were developed such as the Ring and McKee-Farrar implant systems. These early MoM hip systems have been widely referred to as the “first generation” MoM hip implants. These first generation MoM implants failed at an unacceptable rate. They did not reproducibly and reliably provide a long lasting, pain free functional hip articulation for patients. Additionally, adverse bone and soft tissue reactions were common with these MoM prostheses. Revision surgical procedures for failed first generation MoM hip prosthesis were extremely difficult, surgically challenging and often resulted in poor outcomes. Long-term

follow-up of this relatively small number of patients implanted with first generation MOM hip implants was minimal and often anecdotal; however, there was evidence suggesting metal wear debris from these MOM devices caused local and systemic harm to the patients, including the potential risk of carcinogenicity leading to premature failure of the devices, the need for revision surgery, and other serious harm.

In November of 1962, Dr. John Charnley performed the first total hip arthroplasty (THA) utilizing a stainless steel femoral component and high molecular weight polyethylene (HMWP) acetabular component. This construct was the birth of the modern total joint arthroplasty. Metal on polyethylene (MoP) became the standard in THA procedures and it remains the standard today. With the new design and material changes, Dr. Charnley called the new and improved operation a “low friction torque arthroplasty.” He waited approximately 5 years before confirming and announcing to the orthopedic community in 1967, the success of his MoP discovery and the successful results of the MoP surgical procedures. The surgical principles of smaller metal heads and selection of the polyethylene bearing surface material continues to be one of the most efficacious and safest THA option to date and far preferable to the use of MOM bearing surfaces as the risks of those devices outweigh their benefits for the patient. The success, longevity, efficacy and safety of

the MoP procedure have been well documented and proven over several decades. To date, there are multiple 20 and 30-year studies that confirm Charnley's "low friction torque arthroplasty" success utilizing a small metal femoral head and polyethylene acetabular component.

Even with the comparative success of the MoP articulations, the old polyethylene bearing surfaces experienced some wear resulting in polyethylene debris. However, the development of better polyethylene, including highly cross-linked polyethylene during the 1990s and its widespread adoption into the early 2000s, adequately addressed the concerns over polyethylene wear, rendering MoP hip implants a safer and more appropriate implant than MoM hip implants. Medical literature documents the long-term wear properties associated with highly cross-linked polyethylene and the significantly decreased risks to the patient compared to the MoM hip constructs. From 2000 to date, approximately 15 million total hip arthroplasty surgeries have been successfully performed worldwide utilizing cross-linked polyethylene. The risk versus benefit of MoM bearing surface components versus either MoP with highly cross-linked polyethylene or ceramic on polyethylene (CoP) bearing surfaces, in my experience, highly favors the MoP and CoP bearing surface construct over the MoM bearing surface couplings, which includes the

Biomet M2A devices (which includes the Biomet Magnum, M2a 38mm, Magnum Selex, Recap, and Taper modular design options).

My surgical training with hip implants started during my residency at the University of Utah in 1978 and continued through the completion of my additional post-doctorate fellowship training in joint replacement and adult reconstructive surgery at the University of Southern California in 1984. Because of my interest in joint replacement surgery as an orthopedic sub-specialty, I was directly involved in approximately 150 revision surgeries of first generation MoM systems. These included: (1) Ring THAs, (2) McKee-Farrar THAs, and (3) Savish THAs. My extensive exposure to these systems occurred because the primary surgeons responsible for these implantations were the professors that I had the privilege of training under. These surgeons were my mentors and friends including, Sherman S. Coleman, M.D. and Augusto Sarmiento, M.D., both past presidents of the American Academy of Orthopedic Surgeons and founding members of the International and American Hip Societies. Other mentors that helped to shape my perspective on THA, material bearing surfaces, and the surgical implantation of hip devices include, but are not limited to, Harold Dunn, M.D., Wallace Hess, M.D., Lawrence Dorr, M.D., Michael Freeman, M.D. and Robin Ling, M.D. Some of these

above physicians are also International and/or American Hip Society members and all are respected pioneers in the development and use of THA.

My association with the above-referenced physicians, along with my consultation duties for J&J and DePuy, has allowed me the opportunity to collaborate with biomaterial experts, including but not limited to, Harry McKellop, Richard Tarr, Ian Clark, Thomas Gruen, Allen Daniels, and Roy Bloebaum, all of whom are well-respected in their field and have expertise with regard to materials science with regard to hip implant designs. Through my working relationship with these individuals, I gained an appreciation and understanding of biomaterials in total joint arthroplasty. My experience with the above surgeons and biomaterial experts, along with my own practice involved the care and surgical treatment of first generation revisions/failures (and later 2nd generation MoM hip revisions/failures) in MoM hip patients. This experience also involves numerous explant laboratory analyses following implant removal post-revision. During the course of my consultant work with DePuy in the early 2000s, I also expressed my concerns to that medical device manufacturer about the safety and efficacy of use of MoM hip implants in patients.

The late 1990s and early 2000s saw the re-introduction of MoM hip systems in the form of “second generation” MoM total hip replacement (THR) and

resurfacing arthroplasty components. The Biomet MoM hip implants that are the subject of this litigation would be considered part of this “second generation.” Over the more than three decades before this re-introduction, traditional non-MoM bearing surface THRs consistently performed better than the first generation MoM THAs. Because of my training, research, and personal experiences with the revisions/failures of the first generation MoM hip systems, I have never performed a primary/index MoM THA with any of the second generation MoM hip systems, including the Biomet MoM products at issue here, as it was, and continues to be, my opinion as a trained orthopedic surgeon that the risks of use of these MoM devices outweighs their benefits for patients. In particular, the biological risks associated with the generation and production of metal particulate wear debris made me question the safety and efficacy of MoM articulations compared to safer and proven material couplings (i.e.: MoP or CoP). I was also concerned about the lack of long-term safety and efficacy data from Biomet and other manufacturers of MoM devices with regard to the performance of the devices in patients as well as long-term risks of the cobalt-chromium bearing surface and trunnion interfaces.

My long-held concerns about the safety and efficacy of MoM hip implants has been borne out by numerous studies published over the last few years, updated patient safety information from government regulatory agencies, data from

international joint registries, poor patient outcomes documented in my own practice and those of my colleagues (which have been the subject of discussions at professional meetings and various publications), and the fact that many of these MoM products have been formally recalled or are no longer sold.

It is my opinion that the Instructions for Use for the Biomet MoM hip implants, as changed over time, provided insufficient information to orthopedic surgeons to allow them to fully evaluate the risks versus benefits of the Biomet MoM hip implants and make proper recommendations to their patients. It is further my belief that manufacturers of MoM hip implants, including the Biomet MoM hip implants, conducted an insufficient number of studies of the long-term safety of the MoM hip implants to provide adequate information to orthopedic surgeons and patients about the risks versus the utility of the MoM hip implant designs to allow surgeons and patients to make adequate decisions about treatment options and the appropriate devices to be utilized for hip implant procedures from the late 1990s to the present when “second generation” MoM hip implant designs were being sold by Biomet and other medical device manufacturers. Knowledge of the special risks associated with MoM hip implant designs was certainly knowable for the medical device manufacturers such as Biomet during the time period just before and during the marketing of second generation MoM hip implants, but was not well-known to

many practicing orthopedic surgeons, especially those who did not train with surgeons, such as I did, with personal experience relating to early failures of MoM devices.

From the outset of my surgical training to date, I have, time and again, personally seen the negative impact of the significant orthopedic and musculoskeletal damage caused by MoM hip systems implanted in my patients and the patients who have been reported in the medical literature. Specifically, prosthetic-generated metallic wear debris can destroy the soft tissues (i.e.: capsule, tendon/ligament, and muscle), as well as the bony foundation to the hip joint (for example, the pelvis and femur) in implanted patients which leads to pain, poor performance of the MoM hip implant, the need for revision surgeries, and the chance that the patient will have less than optimal results from future hip implant surgeries due to bone and tissue damage caused by the MoM device. Of equal or greater concern are the systemic consequences that can result from the use of MoM bearing surfaces and the metal ion particulate debris they produce in the human body. The risks to patients from metal ion particulate debris is still not well understood due to a lack of definitive studies and testing performed by the manufacturers of the MoM devices, including Biomet, prior to introduction of the products to the market and implantation in patients. These include the development of related malignancies and

bone and tissue damage, which I have witnessed first-hand and which is documented in the published, peer-reviewed scientific and medical literature.

B. Personal Experience with Second Generation MoM hip systems

I have never implanted any MoM articulating coupling as a primary hip implant in my patients due to my longstanding concerns about the safety and efficacy of MoM devices, such as the MoM hip implants manufactured by Biomet. However, I have performed removal/revision surgery on patients with various failed MoM bearings, including the Biomet MoM bearing systems. I have also treated patients who suffer from the multiple complications secondary to the damage caused by MoM articulating interfaces. These complications are very similar to what my early training, research, and personal experiences had been with the revisions/failures of the first generation MoM hip systems.

Because I avoided using the second generation MoM hip implant systems such as the Biomet MoM options, coupled with my satisfaction and success using pre and post-cross-linked MoP and/or CoP in my patients, including Biomet's MoP and CoP hip implant designs, my experience with the MoM devices occurred when patients presented for revisions or clinical follow-up upon referral. In my practice, I started evaluating and treating various patients with MoM implants, including

Biomet M2A MoM hip implants in approximately 2007 and continue to see them today.

In my experience, the primary presenting symptom in MoM hip patients is pain and discomfort. This is often accompanied by decreased activity and in many cases the reliance on and necessity of ambulatory assist devices, such as a cane, crutch, or walker/wheelchair. These patients exhibit a gait abnormality that is not only antalgic (i.e., pain producing), but also reflects muscle deficiency that most often and specifically targets the abductor muscle group (a muscle group that is essential to the proper functioning of an implanted hip implant). This results in a distinctive gait disturbance/abnormality in MoM patients. Patients also frequently present with varying degrees of swelling of the involved extremity. This can vary from subtle to severe and can be noted in the foot and ankle extending all the way to the knee and/or upper thigh. This swelling which is due to obstruction of the vascular supply to the lower extremity is often accompanied by the finding of asymmetrical pulses in the foot and ankle.

Patients can present with complaints of pain in the knee, thigh, lumbar spine, and sacroiliac joint regions, which typically has its root cause at the hip articulation. This presentation at the initiation of the patient's symptoms can be non-specific, nebulous and distract the examiner from the true origin of the pain as it is being

referred from the hip articulation. It is not uncommon for patients who are exhibiting signs of failure of their MoM hip implants to be treated for back or knee pain without addressing the hip implant-related issues due to this confusing presentation of symptoms. Biomet, as well as the other MoM manufacturers, have failed to provide appropriate instructions and warnings to orthopedic surgeons of the signs and symptoms associated with failure of their MoM devices as well as protocol for ongoing monitoring of patients, which contributed to a delay in proper treatment for the failure of some patient's MoM devices.

With these patients, a radiographic analysis including plain films, ultrasound studies, CT scans, and special MRIs routinely demonstrate osteolysis/osteonecrosis, prosthetic loosening, pseudotumors, and/or pathological fractures. Serology (i.e.: blood testing) can demonstrate varying degrees of abnormal elevations of circulating metal ions, including cobalt and chromium. Once soft tissue (capsule, ligament, tendon, and muscle) destruction occurs, it is irreversible and can result in instability manifested by dislocation of the hip articulation. There is an increased risk of multiple complications following a revision surgery, including but not limited to infection and dislocations.

When MoM implant failure occurs in this manner, necrosis of the bone, tendons and tissue can be a direct result of the premature failure of the device. This

outcome can result in permanent damage to the bone and soft tissues adjacent to the patient's implant, which is irreversible.

Complications resulting from the premature failure of the MoM implants, such as the Biomet MoM hip implants, include the likelihood of a patient needing multiple future revision surgeries with increasing complexities of those revision procedures to be expected, especially in light of the bone and tissue damage that often accompany the failure of a MoM hip implant. In comparison to MoP or CoP alternatives, there is an increased risk of late, acute infections with MoM implants, as well.

The majority of failed MoM bearing cases that I have personally evaluated clinically or during surgical revision reveal proper and acceptable component positioning. The prognosis for patients with osteolysis/osteonecrosis, soft tissue destruction, and pathological fracture associated with their implantation with a MoM hip implant is extremely poor.

I have been involved with approximately 45-50 "second generation" revisions and numerous "first generation" revision surgical procedures of MoM hip systems during my career as a Board-certified orthopedic surgeon. In my practice, the use of cross-linked polyethylene with either MoP or CoP has resulted in an extremely low revision rate, and is a far safer and more efficacious alternative to the use of MoM


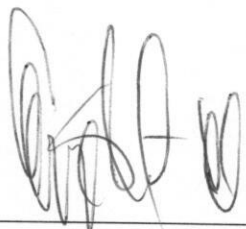
hip implant designs, including the Biomet MoM hip implants at issue here. I have not performed a single revision procedure for wear of a poly acetabular component in over a decade.

I hold each of the stated opinions to a reasonable degree of legal, medical and surgical probability.

V. COMPENSATION AND PAST TESTIMONY

I've worked approximately 45 hours on this case relating to Biomet. My hourly rate is \$500.00/hour for a case related research and \$750.00/hour for out of the office conferences. During the previous 4 years, I have provided trial testimony in the case of McDonald v. Zimmer and deposition testimony in the following cases: Kauthen v. DePuy, Woods v. Wright Medical, Powers v. Wright Medical, Rizika v. Wright Medical, Diano v. Zimmer NexGen, and Pudwell v. Zimmer NexGen.

Dated February 23, 2017.



GEORGE S. KANTOR, M.D.

EXHIBIT “A” TO EXPERT REPORT OF GEORGE S. KANTOR, M.D. –
CURRICULUM VITAE

CURRICULUM VITAE

GEORGE S. KANTOR, M. D.

PERSONAL BACKGROUND AND INFORMATION

| | |
|-------------------|--|
| NAME: | GEORGE STEPHEN KANTOR, M. D. |
| PRIVATE PRACTICE: | 11211 Prosperity Farms Road, Suite C114 Palm Beach Gardens, Florida 33410 (September 1983 – present) |
| OFFICE PHONE: | (561) 622-2546 |
| OFFICE FAX: | (561) 627-1757 |
| DATE OF BIRTH: | March 8, 1949 |
| PLACE OF BIRTH: | Yonkers, New York |
| CITIZENSHIP: | United States |

EDUCATION AND DEGREES

| | |
|-----------------|--|
| HIGH SCHOOL: | Peekskill Academy Peekskill, New York (1967) |
| COLLEGE: | Tulane University New Orleans, Louisiana (B. A., 1971) [1967-1971] |
| MEDICAL SCHOOL: | Tulane University New Orleans, Louisiana (M. D., 1977) [1973-1977] |
| INTERNSHIP: | Tulane University New Orleans, Louisiana Flexible Surgical Internship [1977-1978] |
| RESIDENCY: | University of Utah Salt Lake City, Utah Orthopaedic Residency [1978-1982] |

FELLOWSHIP:

University of Southern California
Los Angeles, California
Adult Reconstruction/Arthritis Surgery
[1982-1983]

LICENSURE/CERTIFICATION

FLORIDA MEDICAL LICENSE

ME0042161

BOARD CERTIFICATION

American Board of Orthopaedic Surgery
1986 (Acceptance at first sitting)

ABOS Recertification, July 1998

ABOS Recertification, July 2009

ABOS Recertification through 12/31/20

MEDICAL HONORS AND AWARDS

“Golden Scalpel Award” for Outstanding Surgical Intern, Charity Hospital, 1977-1978

“Albert E. Klinkicht Award,” American Orthopaedic Foot Surgery, 1981

Chief Resident, University of Utah, Orthopaedic Residency, 1981-1982

HONORS AND AWARDS

Reisch Turnisha Scholarship, Academic/Athletic Excellence, Westchester County, 1967

Varsity Football, Tulane University, New Orleans, Louisiana, 1969-1970

Deans List, Tulane University; 1969, Spring Semester, 1971, Spring Semester, named consecutively

B. A. Tulane University with High Honors

PRESENTATIONS

Investigation of Lateral Ligament Reconstruction, American Academy of Orthopaedic Surgeons, Las Vegas, Nevada, 1981.

Pelvic Osteotomy for the Treatment of Adolescent Hip Dysplasia, Shrine Hospitals Scientific Meetings, Salt Lake City, Utah, 1982.

Histomorphometric Analysis of Bone, Western Orthopaedic Society, 1993.

Salter Osteotomy for the Treatment of Acetabular Dysplasia in the Adolescent, American Academy of Orthopaedic Surgeons, Atlanta, Georgia, 1984.

Resection Arthroplasty for Infected Total Hip Arthroplasty, American Academy of Orthopaedic Surgeons, Las Vegas, Nevada, 1985.

The Girdlestone Hip Following Infected Total Hip Arthroplasty, Florida Orthopaedic Society, Key Largo, Florida, 1987.

PUBLICATIONS

Horstman, J.K., Kantor, G.S., and Samuelson, R.M.; "Investigation of Lateral Ankle Reconstruction," Foot and Ankle, November 1981.

Kantor, G.S., Dorr, L.D., and Malluche, H.; "Histomorphometric Analysis of Bone Adjacent to Cemented Femoral Prosthesis in Rheumatoid and Osteoarthritis," Clinical Orthopaedic, No. 205, May 11, 1985.

Kantor, G.S., Osterkamp, J.A., Dorr, L.D., Fischer, D., Perry, J., Conaty, J.P.; "Resection Arthroplasty Following Infected Total Hip Replacement Arthroplasty," The Journal of Arthroplasty, Volume 1, Number 2, October 1986.

Kantor, G.S., Coleman, S.S.; "Salter Osteotomy for the Treatment of Acetabular Dysplasia in the Adolescent," The Journal of Bone and Joint Surgery

Kantor, George S., M.D., Hartrick, Craig, M.D., DABPM, FIPP, Durieux, Marcel E., M.D., Ph.D., Gould, Errol M., Ph. D.; "Extended -Release Epidural Morphine for Pain after Total Hip Arthroplasty," The Journal of Bone and Joint Surgery, 2004.

Hartrick, Craig, M.D., Martin, Gavin, M.D., Kantor, George, M.D., Koncelik, John, D.O., Manvelian, Garen, M.D.; "Evaluation of DepoDur, A Single-Dose, Extended- Release Epidural Morphine Formulation for Pain After Knee Arthroplasty," The Journal of Bone and Joint Surgery, 2005.

APPOINTMENT/POSITIONS

Johnson and Johnson Orthopedics, Inc. Clinical Consultant and Surgical Instructor 1990-1997.

DePuy Orthopaedics, Inc., Clinical Consultant and Surgical Instructor 1997-2009.

M. D. Network, Medical Director/Consultant, Physical Therapy/Occupational Therapy and Rehabilitation, 1997-January 2005

The Gardens Court, Medical Director of Rehabilitation, 2001-December 2005

Chatsworth at PGA National, Medical Director of Rehabilitation, August 2001-2011

The Waterford, Medical Director of Rehabilitation December 2011-2012

Chairman Dept. of Orthopaedics, Palm Beach Gardens Medical Center, 1998-1999, 2002-2004

Chairman Dept. of Orthopaedics, St. Mary's Medical Center. 2008-2015

Vice Chief of Staff, Palm Beach Gardens Medical Center, 2000-2002

Vice Chief of Surgery, Palm Beach Gardens Medical Center, 2000-2002

Palm Beach Gardens Medical Center, Medical Council, 2000-2002

Spokesperson, Tenet Southeast Regional Total Joint Program, 1996-2012

Presidential Advisory Council Tulane University 2008- present

Governing Board of Directors Tulane University Medical School 2011-present

RESEARCH

Sanofi Research, Principal Investigator, Phase II and Phase III Clinical Trial, Antithrombotic/DVT prevention in elective primary total hip replacement and revision total hip replacement, 1997-1999.

Organon, Inc., Principal Investigator, Phase III Clinical Trial, Antithrombotic/DVT prevention in elective primary total knee replacement and revision total knee replacement, 1998-1999.

AstraZeneca, Principal Investigator, Phase III Clinical Trial, Antithrombotic/ DVT prevention in elective primary total hip replacement (Protocol 237) and elective primary total knee replacement (Protocol 236 and Protocol 290A and 290B), June 2000-April 2003.

SkyePharma, Inc., Principal Investigator, Phase II/III Clinical Trial, Management of Post-Operative Pain in Patients Undergoing Knee Arthroplasty (Protocol SKY0401-017), June 2002-April 2003.

Bayer Pharmaceuticals, Principal Investigator, Phase II Clinical Trial, Antithrombotic/DVT prevention in elective total knee replacement (Bayer Protocol 10945), May 2004-September 2004.

Endo Pharmaceuticals, Principal Investigator, Phase IV Clinical Trial, Management of Post-Operative Pain in Patients Undergoing Hip Arthroplasty with Regional Anesthesia (Protocol SKY0401-019), August 2004-May 2005.

HOSPITAL AFFILIATIONS

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REFERENCES

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**EXHIBIT “B” TO EXPERT REPORT OF GEORGE S. KANTOR, M.D. –
RELIANCE MATERIALS**

All material relied upon in the Expert Witness Report of George S. Kantor, M.D.

1. Algarni A, et al. Metallosis-induced Iliopsoas Bursal Cyst Causing Venous Obstruction and Lower-limb Swelling After Metal-on-metal THA: Case Report. Spotlight on THA. Healio.com/Orthopedics. doi: 10.3928/01477447-20121120-30: 1066-1069.
2. Amstutz, H., et al., Metal on Metal Total Hip Replacement Workshop Consensus Document, Clinical Orthopaedics and Related Research (1996), No. 329S, pp. 297-303.
3. Anand A, et al. Metal Hypersensitivity: Can it Mimic Infection? The Journal of Arthroplasty, 2009; 24(5): 826.e25-e28.
4. Berend, K., et al., Metal-on-Metal Hip Arthroplasty – going, going, gone – affirms, The Bone & Joint Journal (2012).
5. Bernstein, D. et al. The Orthopaedic Forum: Eighty-six Percent Failure Rate of a Modular-Neck Femoral Stem Design at 3 to 5 Years. The Journal of Bone and Joint Surgery, 2016; 98:e49(1-7).
6. Bernthal NM, Celestre PC, Stavrakis AI, Ludington JC, Oakes DA. Disappointing Short-Term Results With The DePuy ASR XL Metal-on-Metal total Hip Arthroplasty. Journal of Arthroplasty. 2012; 27(4): 539-544.
7. Berry D. Why I Chose This Technology For My Practice And Patients: Highly Cross-Linked Polyethylene in THR. Symposium I from the AAHKS Fifteenth Annual Fall Meeting
8. Bishop, Nicholas, et al. Wear Patterns of Taper Connections in Retrieved Large Diameter Metal-on-Metal Bearings, Journal of Orthopaedic Research, 2013, 1.
9. Bitsch R, et al. Reduction of Osteolysis with Use of Marathon Cross-Linked Polyethylene. The Journal of Bone and Joint Surgery, 2008; 90-A(7): 1487-1491.
10. Black A. Biological Performance of Materials: Fundamentals of Biocompatibility. CRC Press, 1996. All references contained therein.
11. Black J. Metal on metal bearings. A practical alternative to metal on polyethylene total joints? Clinical Orthopaedics and Related Research, 1996; 329 Suppl.: S244-55.
12. Bosker B.H., et al. High Incidence of Pseudotumour Formation After Large-Diameter Metal-on-Metal Total Hip Replacement. The Journal of Bone & Joint Surgery, 2012; 94-B(6): 755-761
13. Bosker B.H., et al. Pseudotumor formation and serum ions after large head metal-on-metal stemmed total hip replacement. Risk Factors, time course, and revision in 706 hips. Archives of Orthopaedic and Trauma Surgery, 2015; 135: 417-425.

14. Bouchard P.R., et al. Carcinogenicity of CoCrMo (F-75) implants in the rat. *Journal of Biomedical Materials Research*, 1996; 32(1): 37-44.
15. Brodner W, et al. Elevated Serum Cobalt with Metal-on-Metal Articulating Surfaces. *British Editorial Society of Bone and Joint Surgery*, 1997; 79-B: 316-21.
16. Bruze M. Thoughts on Implants and Contact Allergy. *Archives of Dermatology*, 2008; 144(8): 1042-1044.
17. Campbell et al. Histological Features of Pseudotumor-like Tissues From Metal-on-Metal Hips. *Clinical Orthopaedics and Related Research*, 2010; 468(9): 2321-2327.
18. Carli, A., et al. Clinically significant corrosion at the head-neck taper interface in total hip arthroplasty: a systematic review and case series. *Hip International*, 2015; 25 (1): 7-14.
19. Case C.P, et al. Widespread Dissemination of Metal Debris from Implants. *The Journal of Bone and Joint Surgery*, 1994; 76-B: 701-12.
20. Cogan N, et al. DNA damaging bystander signaling from stem cells, cancer cells and fibroblasts after Cr(VI) exposure and its dependence on telomerase. *Mutat. Res.*, 2010; 683(1-2): 1-8.
21. Collier J, et al. Corrosion Between the Components of Modular Femoral Hip Prostheses. *The Journal of Bone and Joint Surgery*, 1992; 74-B: 511-7.
22. Cooper, J. et al. Adverse Local Tissue Reaction Arising from Corrosion at the Femoral Neck-Body Junction in a Dual-Taper Stem with a Cobalt-Chromium Modular Neck. *Journal of Bone and Joint Surgery [Am]*, 2013; 95-A(10): 865-872.
23. Cooper, J. et al. Corrosion at the Head-Neck Taper as a Cause for Adverse Local Tissue Reactions After Total Hip Arthroplasty. *Journal of Bone and Joint Surgery [Am]*, 2012; 94: 1655-1661.
24. Cramers M, et al. Metal Sensitivity in Patients Treated for Tibial Fractures with Plates of Stainless Steel. *Acta. orthop. scand*, 1977; 48: 245-249.
25. Daou S, et al. Cobalt ions (Co²⁺) Decrease Neutrophils Antibacterial Activity by Inhibiting Hv1 Proton Channels. Paper presented at AAOS 2011: Rehabilitation; Paper 622.
26. Daou S, et al. The potential role of cobalt ions released from metal prostheses on inhibition of Hv1 proton channels and the decrease in *Staphylococcus epidermidis* killing by human neutrophils. *Biomaterials*, 2011; 32: 1769-77.
27. Day C.S., et al. The Orthopaedic Forum, Analysis of FDA-Approved Orthopaedic Devices and Their Recalls. *The Journal of Bone and Joint Surgery*, 2016; 98:517-24.

28. Donaldson JR, et al. The relationship between the presence of metallosis and massive infection in metal-on-metal hip replacements. *Hip International*, 2010; 20(2): 242-47.
29. Doyle K. High risk medical devices backed by few studies. Reuters, August 13, 2015.
30. Duwelius, P. et al. Modular vs. Nonmodular Neck Femoral Implants in Primary Total Hip Arthroplasty: Which is Better? *Clinical Orthopaedics and Related Research*. 2014; 472: 1240 – 1245.
31. Earll M, et al. Wound Drainage After Metal-On-Metal Hip Arthroplasty Secondary to presumed Delayed Hypersensitivity Reaction. *The Journal of Arthroplasty*, 2011; 26(2) 338e5-7.
32. Engh C.A, et al. Metal Ion levels After Metal-on-Metal Total Hip Arthroplasty. *The Journal of Bone and Joint Surgery*, 2014; 96-A(6): 448-455.
33. Engh C.A., et al. A Randomized Prospective Evaluation of Outcomes After Total Hip Arthroplasty Using Cross-linked Marathon and Non-cross-linked Enduron Polyethylene Liners. *The Journal of Arthroplasty*, 2006; 21(6): 17- 25.
34. Estok D, et al. Comparison of Hip Simulator Wear of 2 Different Highly Cross-Linked Ultra High Molecular Weight Polyethylene Acetabular Components Using Both 32- and 38-mm Femoral Heads. *The Journal of Arthroplasty*, 2007; 22(4): 581-589.
35. Evans E, et al. Metal Sensitivity As A Cause of Bone Necrosis and Loosening of the Prosthesis in Total Joint Replacement. *The Journal of Bone and Joint Surgery*, 1974; 56-B: 626-42.
36. Gagnier J, Kellam P. Reporting and Methodological Quality of Systematic Reviews in the Orthopaedic Literature. *Journal of Bone and Joint Surgery [Am]*, 2013; 95-A(10): 1055.
37. Galbraith J, et al. Infection or metal hypersensitivity? The diagnostic challenge of failure in metal-on-metal bearings. *Acta Orthop. Belg.*, 2011; 77: 145-151.
38. Ganzer D, et al. Two-year follow-up of revision total hip arthroplasty using a ceramic revision head with a retained well-fixed femoral component: a case series. *Journal of Medical Case Reports*, 2014; 8: 434.
39. Gao X, et al. Dermatitis Associated with Chromium Following Total Knee Arthroplasty. *The Journal of Arthroplasty*, 2011; 26(4): 665.e13-665.e16.
40. Garbuz DS, et al. Large (36 or 40-mm) Femoral Heads Decreased the Rate of Dislocation After Revision Total Hip Arthroplasty: Commentary. *The Journal of Bone and Joint Surgery [Am]*, 2012; 94-A(22): 2095.
41. Garvin K. Tapering Our Focus to the Causes and Correction of Metallosis in Primary Total Hip Arthroplasty: Commentary on an article by Brett R. Levine, MD, MS et al.:

- “Ten-Year Outcome of Serum Metal Ion Levels After Primary Total Hip Arthroplasty: A Concise Follow-up of a Previous Report”. *Journal of Bone and Joint Surgery [Am]*, 2013; 95-A(6): 576.
42. Gillespie WJ, et al. The Incidence of Cancer Following Total Hip Replacement. *The Journal of Bone and Joint Surgery*, 1988; 70-B(4): 539-542.
43. Grammatopoulos G, et al. Hip resurfacings revised for inflammatory pseudotumour have a poor outcome. *The Journal of Bone and Joint Surgery*, 2009; 91-B(8): 1019-24.
44. Graves S, et al.; Paper #179, “Specific MoM hip implant linked with increased risk of heart failure in men”; Presented at: American Academy of Orthopaedic Surgeons Annual Meeting; March 1 – 5, 2016; Orlando, FL.
45. Gross T.P., et al. Hip Resurfacing With the Biomet Hybrid ReCap-Magnum System – 7-Year Results. *The Journal of Arthroplasty*, 2012; 27(9): 1683-1689.
46. Haag M, et al. Malignant Fibrous Histiocytoma in Association with Hip Replacement. *The Journal of Bone and Joint Surgery [Br]*, 1989; 71-B(4): 701.
47. Hallab N, et al. Th1 type lymphocyte reactivity to metal in patients with total hip arthroplasty. *Journal of Orthopaedic Surgery and Research*, 2008; 3(6): 1-11.
48. Hamilton W, et al. Incidence of Reoperation and Reasons for Reoperation After Minimally Invasive Unicompartamental Knee Arthroplasty. Paper #9 presented at the AAHKS Fifteenth Annual Fall Meeting.
49. Hannouche D, et al. Is There a Risk in Placing a Ceramic Head on a Previously Implanted Trunion? *Clinical Orthopaedics and Related Research*, 2010; 468: 3322-27.
50. Heath JC, et al. Carcinogenic Properties of Wear Particles from Prostheses Made in Cobalt-Chromium Alloy. *The Lancet*. March 20, 1971.
51. Heath JC, et al. The Interaction of Carcinogenic Metals with Tissues and Body Fluids: Cobalt and Horse Serum. *British Journal of Cancer*, 1969; 23(1):153-66.
52. Heisel C, et al. Short-Term In Vivo Wear of Cross-Linked Polyethylene. *The Journal of Bone and Joint Surgery*, 2004; 86-A(4): 748-751.
53. Helwig P, et al. Modular sleeves with ceramic heads in isolated acetabular cup revision in younger patients – laboratory and experimental analysis of suitability and clinical outcomes. *International Orthopedics*, 2013; 37(1): 15-19.
54. Heselson NG, et al. Two Malignant Fibrous Histiocytomas in Bone Infarcts: Case Report. *The Journal of Bone and Joint Surgery*, 1983; 65-A(8): 1166-1171.

55. Huang D, et al. Cumulative revision Rate is Higher in Metal-on-Metal THA than Metal-on-Polyethylene THA: Analysis of Survival in a Community Registry. *Clinical Orthopaedics and Related Research*, 2013; 471: 1920-1925.
56. Hug KT, Watters TS, Vail TP, Bolognesi MP. The Withdrawn ASR THA and Hip Resurfacing Systems/How Have Our Patients Fared Over 1 To 6 Years? *Clin. Orthop. Relat. Res.*, 2013; 471:430-438.
57. Hutt J, et al. Comparison of Whole-Blood Metal Ion Levels Among Four Types of Large-Head, Metal on Metal Total Hip Arthroplasty Implants, A Concise Follow-up, at Five Years, of a Previous Report. *The Journal of Bone and Joint Surgery*, 2016; 98:257-66.
58. Jacobs C, et al. Clinical Performance of Highly Cross-Linked Polyethylenes in Total Hip Arthroplasty. *The Journal of Bone and Joint Surgery*, 2007; 89-A(12): 2779-2786.
59. Jameson S.S., et al. Independent Predictors of Revision Following Metal-on-Metal Hip Resurfacing. *The Journal of Bone & Joint Surgery*, 2012; 94-B: 746-54
60. Johnston R, et al. Charnley Total Hip Arthroplasty With Use Of Improved Cementing Techniques. *The Journal of Bone and Joint Surgery*. 2001; 83-A(12): 1840-48.
61. Judd K, Noiseux N. Concomitant Infection and Local Metal Reaction in Patients Undergoing Revision of Metal on Metal Total Hip Arthroplasty. *The Iowa Orthopaedic Journal*, 2011; 31: 59-63.
62. Kantor GS, et al. Resection arthroplasty following infected total hip replacement. *The Journal of Arthroplasty*, 1986; 1(2): 83-9.
63. Keegan GM, et al. A systematic comparison of the actual, potential, and theoretical health effects of cobalt and chromium exposures from industry and surgical implants. *Crit. Rev. Toxicology*, 2008; 38(8): 645-674.
64. Keegan, G.M., et al. Orthopaedic metals and their potential toxicity in the arthroplasty patient. *The Journal of Bone and Joint Surgery*, 2007; 89-B(5): 571.
65. Kim YH, et al. Polyethylene Wear and Osteolysis After Cementless Total Hip Arthroplasty with Alumina-on-Highly cross-Linked Polyethylene Bearings in Patients Younger Than Thirty Years of Age. *The Journal of Bone and Joint Surgery*, 2013; 95-A(12) 1088 – 1093.
66. Klapach A, et al. Charnley Total Hip Arthroplasty with Use of Improved Cementing Techniques: A Minimum Twenty-Year Follow-Up Study. *The Journal of Bone and Joint Surgery*, 2001; 83-A(12): 1840-1848.
67. Ladon D, et al. Changes in metal levels and chromosome aberrations in the peripheral blood of patients after metal-on-metal hip arthroplasty. *Journal of Arthroplasty*, 2004; 19(8 Suppl. 3): 78-83.

68. Langton DJ, Jameson SS, Joyce TJ, Gandhi JN, Sidaginamale R, Mereddy P, Lord J, Nargol AV J. Accelerating Failure Rate of the ASR Total Hip replacement. *Bone Joint J Bone Joint Surg Br.* 2011; 93(8): 1011-1016.
69. Lardanchet, J.F., et al. One-year prospective comparative study of three large-diameter metal-on-metal total hip prostheses: Serum metal ion levels and clinical outcomes. *Orthopaedics & Traumatology: Surgery & Research*, 2012; 98: 265-274.
70. Latteier M.J., et al. Gender is a Significant Factor for Failure of Metal-on-Metal Total Hip Arthroplasty. *The Journal of Arthroplasty*, 2011; 26(6): 19-23.
71. Lavigne, M., Comparison of Whole-Blood Metal Ion Levels in Four Types of Metal-on-Metal Large-Diameter Femoral Head Total Hip Arthroplasty: The Potential Influence of the Adapter Sleeve, *JBJS* (2011), http://jbjs.org/content/93/supplement_2/128.
72. Learmonth ID, et al. Metallic debris from orthopaedic implants. *The Lancet*, 2007; 369(9561): 542-544.
73. Lee J, et al. Vascular Tumor in Metal-on-polyethylene THA requiring Hemipelvectomy. *Orthopedics*, 2013; 36(7): e974-e977.
74. Levine B, et al. Ten-Year Outcome of Serum Metal Ion Levels After Primary Total Hip Arthroplasty: A Concise Follow-up of a Previous Report. *Journal of Bone and Joint Surgery [Am]*, 2013; 95-A(6): 512-518.
75. Lombardi A, et al. The Hip Society: Algorithmic Approach to Diagnosis and Management of Metal-on-Metal Arthroplasty. Presented as Scientific Exhibit #06 at the 2012 Annual Meeting of the American Academy of Orthopaedic Surgeons, San Francisco, California, Feb. 7-12, 2012.
76. Lombardi, A., et al., The dual mobility policy liner: A worthwhile articulation choice?, *Seminars in Arthroplasty*, <http://dx.doi.org/10.1053/j.sart.2011.04.005>.
77. Malchau H, et al. The Swedish Total Hip Replacement Register. *Journal of Bone and Joint Surgery [Am]*, 2002; 84-A(Suppl. 2): 2-20.
78. Manner P. A Spoonful of Sugar: Commentary on an article by Adams A, et al. "Surgical Outcome of Total Knee Replacement According to Diabetes Status and Glycemic Control, 2001 to 2009". *Journal of Bone and Joint Surgery [Am]*, 2013; 95- A(6): 576.
79. Mantymaki, H., et al., Modular to Monoblock: Difficulties of Detaching the M2-a-Magnum Head Are Common in Metal-on-Metal Revisions, *Clin Orthop Relat Res* (2016) 474:1999-2005.
80. Martell J, et al. Clinical Performance of a Highly Cross-Linked Polyethylene at Two Years in Total Hip Arthroplasty: A Randomized Prospective Trial. *The Journal of Arthroplasty*, 2003; 18(7 Suppl. 1): 55-59.

81. Martin, J.R., et al. Cardiac cobaltism: a rare complication after bilateral metal-on-metal total hip arthroplasty. *Arthroplasty Today*, 2015: 1-4.
82. Matsen, L, et al. Catastrophic Femoral Head-Stem Trunnion Dissociation Secondary to Corrosion. *The Journal of Bone & Joint Surgery*, 2016; 98: 1400 – 4.
83. Maurer-Ertl W, et al. Noninflammatory Pseudotumor Simulating Venous Thrombosis After Metal-on-Metal Hip Resurfacing: Case Report. *Orthopedics Today*. www.ORTHOSuperSite.com. doi: 10.3928/01477447-20110826-32: 808.
84. McCarthy JC, et al. Custom and modular components in primary total hip replacement. *Clinical Orthopaedics and Related Research*, 1997; 334: 162-71.
85. Merritt K, et al. Tissue Reaction and Metal Sensitivity: An Animal Study. *Acta. orthop. scand.*, 1980; 51: 403-411.
86. Mesinkovska N, et al. The Effect of Patch Testing on Surgical Practices and Outcomes in Orthopedic Patients With Metal Implants. *Archives of Dermatology*, 2012; 148(6): 687-692.
87. Mihalko, W. et al. How Have Alternative Bearings and Modularity Affected Revision Rates in Total Hip Arthroplasty? Symposium: ABJS Carl T. Brighton Workshop on Implant Wear and Tribocorrosion of Total Joint Replacements. *Clinical Orthopaedics and Related Research*, Dec. 2014, Vol 472, Issue 12, pp 3747 – 3758.
88. Mokka J, et al. Adverse reaction to metal debris after ReCap-M2A-Magnum large-diameter-head metal-on-metal total hip arthroplasty. *Acta Orthopaedica*, 2013; 84(6): 549-554.
89. Molli, R.G., Metal-on-Metal vs. Metal-on-Improved Polyethylene Bearings in Total Hip Arthroplasty. *The Journal of Arthroplasty*, 2011; 26(6)-1: 8-13.
90. Molloy DO, et al. Fretting and corrosion in modular-neck total hip arthroplasty femoral stems. *Journal of Bone and Joint Surgery [Am]*, 2014; 96(6): 488-93.
91. Morlock M. The taper disaster – how could it happen? *Hip International*, 2015; 00: 1-8.
92. Morlock, M., et al., Primary hip replacement stem taper fracture due to corrosion in 3 patients. *Acta Orthopaedica*, 2016, 87.
93. Morlock, M., et al. Corrosion of the Head-Stem Taper Junction – Are We on the Verge of an Epidemic?, *HSS Journal*, October 2016, Vol. 12, No. 3.
94. Muratoglu K, et al. Larger Diameter Femoral Heads Used in Conjunction With a Highly Cross-Linked Ultra-High Molecular Weight Polyethylene. *The Journal of*

Arthroplasty, 2001; 16(8) Suppl. 1:24-30.

95. Nakahara I, et al. Minimum of Five-Year Follow-Up Wear Measurement of Longevity Highly Cross-Linked Polyethylene Cup Against Cobalt-Chromium or Zirconia Heads. *The Journal of Arthroplasty*, 2010; 25(8): 1182-1187.
96. Nawabi D, et al. Magnetic Resonance Imaging Findings in Symptomatic Versus Asymptomatic Subjects Following Metal-on-Metal Hip Resurfacing Arthroplasty. *Journal of Bone and Joint Surgery [Am]*, 2013; 95-A(10): 895-902.
97. Nawabi, D, et al. Comprehensive Analysis of a Recalled Modular Total Hip System and Recommendations for Management. *Journal of Bone and Joint Surgery [Am]*, 2016; 98: 40-47.
98. Nikolaou, V.S., et al. Metal-on-Metal Total Hip Arthroplasty – Five to 11-year Follow-Up. *Bulletin of the NYU Hospital for Joint Diseases*, 2011; 69(1): 77-83.
99. Nyren O, McLaughlin J, et al. Cancer Risk After Hip Replacement with metal Implants: a Population-Based Cohort Study in Sweden. *Journal of the National Cancer Institute*, 1995; 87(1): 28-33.
100. Pagnano M, et al. Patients Preferred a Mini-Posterior Total Hip Arthroplasty Over a Contralateral Two-Incision Total Hip Arthroplasty: Results in Patients Treated with the Same Anesthetic and Rehab Protocol. Paper #11 presented at the AAHKS Fifteenth Annual Fall Meeting.
101. Pagnano M, et al. Two-Incision Total Hip Arthroplasties Had Modest Outcomes and Some Substantial Complications. Paper #10 presented at the AAHKS Fifteenth Annual Fall Meeting.
102. Pandit H, et al. Pseudotumours associated with metal-on-metal hip resurfacings. *The Journal of Bone and Joint Surgery*, 2008; 90-B(7): 847-851.
103. Parvizi J, et al. Minimally Invasive Hip Arthroplasty: Surgeons vs. Patients Prospective. Paper #12 presented at the AAHKS Fifteenth Annual Fall Meeting.
104. Pelt C, et al. Histologic, Seologic, and Tribologic Findings in Failed Metal-on-Metal Total Hip Arthroplasty. *The Journal of Bone and Joint Surgery [Am]*, 2013; 95(e163): 1-11.
105. Plummer, D. et al. Diagnosis and Management of Adverse Local Tissue Reactions Secondary to Corrosion at the Head-Neck Junction in Patients With Metal on Polyethylene Bearings. *The Journal of Arthroplasty*. 2016; 31: 264 – 268.
106. Post Z, et al. Metal Sensitivity After TKA Presenting With Systemic Dermatitis and Hair Loss. *Orthopedics*. Healio.com; doi:10.3928/01477447-20130327-35.
107. Qu, X, et al. Metal-on-metal or metal-on-polyethylene for total hip arthroplasty: a

- metal-analysis of prospective randomized studies. Archives of Orthopaedic and Trauma Surgery, 2011, 131: 1573-1583.
108. Rae T. The action of cobalt, nickel and chromium on phagocytosis and bacterial killing by human polymorphonuclear leucocytes; relevance to infection after total arthroplasty. Biomaterials, 1983; 4: 175-180.
109. Reito A, Puolakka T, et al. High Prevalence of Adverse Reactions to Metal Debris in Small-headed ASR Hips. Clinical Orthopaedics and Related Research, 2013 Apr 30.
110. Repantis T, et al. Poor Mid-Term Survival of the Low-Carbide Metal-on-Metal Zweymüller-Plus Total Hip Arthroplasty System: A Concise Follow-up, at a Minimum of Ten Years, of a Previous Report. Journal of Bone and Joint Surgery [Am], 2013; 95-A(6): 535.
111. Riew D. Adjacent-Segment Range of Motion Following Anterior Cervical Fusion: Commentary on an article by Anderst W, et al.: "Six Degrees-of-Freedom Cervical Spine Range of Motion During Dynamic Flexion Extension After Single-Level Anterior Arthrodesis. Comparison with Asymptomatic Control Subjects". Journal of Bone and Joint Surgery [Am], 2013; 95-A(6): 576.
112. Schey JA. Systems view of optimizing metal on metal bearings. Clinical Orthopaedics and Related Research, 1996; 329 Suppl.:S115-27.
113. Shimizu K, et al. Iliopsoas Muscle Atrophy Pre and Post THA – MRI Analysis of 500 Cases. Paper presented at AAOS 2011: Rehabilitation; Paper 619.
114. Sidaginamale R, et al. Blood metal ion testing is an effective screening tool to identify poorly performing metal-on-metal bearing surfaces. British Editorial Society of Bone and Joint Surgery, 2013; 2(5): 84-95.
115. Sidaginamale, R. et al. Blood Metal ion Testing is an effective screening tool to identify poorly performing metal-on-metal bearing surfaces. Bone Joint Res. 2013; 2: 84-95.
116. Simonsen LO, et al. Cobalt metabolism and toxicology – a brief update. Science of the Total Environment, 2012; 432: 210-5.
117. Smith A, et al. Failure rates of stemmed metal-on-metal hip replacements: analysis of data from the National Joint Registry of England and Wales. The Lancet, Mar 13, 2012; doi:10.1016/S0140-6736(12)60353-5.
118. Steele GD, Fehring TK, Odum SM, Denny AC, Nadaud MC. Early Failure of Articular Surface Replacement XL Total Hip Arthroplasty. Journal of Arthroplasty. 2011; 26(6 Suppl): 14-18.
119. Tait NP, et al. Malignant fibrous histiocytoma occurring at the site of a previous total hip replacement. The British Journal of Radiology, 1988; 61:73-76.

120. Thakur R, et al. Severe Persistent Synovitis After Cobalt-chromium Total Knee Arthroplasty Requiring Revision. *Orthopedics*. Healio.com; doi:10.3928/01477447-20130327-34
121. Trace, R. Soft tissue reactions to metal-on-metal arthroplasty are due mostly to surface wear. *Orthopedics Today*. www.ORTHOSuperSite.com. 2009 Nov.
122. Troop JK, et al. Malignant fibrous histiocytoma after total hip arthroplasty. A case report. *Clin. Orthop. Relat. Res.*, 1990; (253): 297-300.
123. Vahey JW, et al. Carcinogenity and metallic implants. *American Journal of Orthopaedics*, 1995; 24(4): 319-324.
124. Vail T. Minimally Invasive Surgery: The Issues: Minimal Single Incision Posterior THA. Symposium II from the AAHKS Fifteenth Annual Fall Meeting.
125. Visuri T, et al. Cancer risk after Mckee-Farrar total hip replacement. *Orthopedics*, 1991; 14(2): 137-142.
126. Whitwell GS. Significant increase in failure rates of MoM designs predicted. *Hip International*, 2012.
127. Willert HG, et al. Metal-on-Metal Bearings and Hypersensitivity in Patients with Artificial Hip Joints: A Clinical and Histomorphological Study. *The Journal of Bone and Joint Surgery [Am]*, 2005; 87(1): 28-36.
128. Witt, F., et al., The Relation Between Titanium Taper Corrosion and Cobalt-Chromium Bearing Wear in Large-Head Metal-on-Metal Total Hip Prostheses, *J. Bone Joint Surg Am*, 2014; 96:e157(1-9).
129. Woolson S, et al. Primary Total Hip Replacement with Insertion of an Acetabular Component without Cement and a Femoral Component with Cement. *The Journal of Bone and Joint Surgery*, 1996; 78-A(5): 698-705.
130. Zylberberg A, et al. Trunnion Corrosion as a Cause of Reccurent Pseudotumor. *Hospital of Special Surgery Journal*, 2015; 11:90-9.
131. Depositions taken in MDL and state court proceedings involving Biomet metal-on-metal hip implants, including exhibits.
132. Regulatory and manufacturer materials relating to metal-on-metal hip implant safety alerts and product recalls.
133. Internal Biomet documents produced in the litigation or to be produced in the future.
134. Biomet design file produced in the state and federal court litigation.
135. Instructions for Use produced in the litigation by Biomet

